



SILICONIZATION

A UNIQUE TREATMENT PROCESS PROTECTING AND ADDING VALUE TO YOUR PHARMACEUTICAL PRODUCT







KEY FEATURES & BENEFITS OF SILICONIZATION



SGD Pharma siliconized vials are the ideal high performance packaging solution for sensitive pharmaceutical applications. Siliconization provides added protection to your robust, premium glass containers helping you to maximize the value of your pharmaceutical product.

Siliconization is available for:

- Molded glass in Type I, II or III
- All vials from 5ml to 500ml
- Clear or amber glass

SILICONISATION ADVANTAGES:

Barrier coating for Parenteral and Nasal drugs

- Provides a protective layer useful for fragile molecules, further **minimizing the interactions** between the drug and the container,
- Improves **chemical durability** for alkaline solutions.

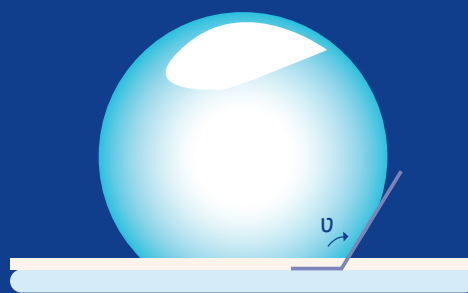
Enhanced hydrophobic property for all the pharma applications

- Prevents **high viscosity infusions from sticking** to the internal surface of the vials, giving them a perfect transparency and easy inspection,
- Ensures that **every last drop of product is utilized**.

Drop of water on the glass surface



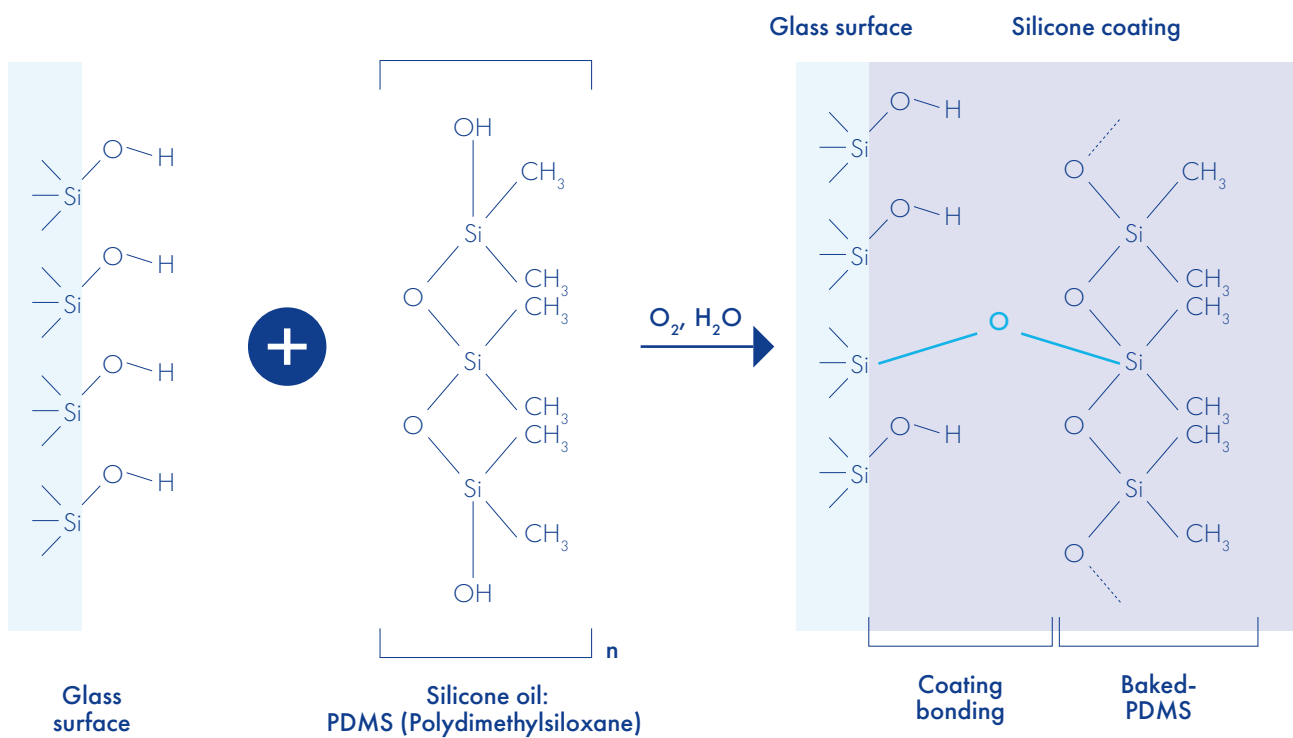
Non siliconized surface: $\theta < 90^\circ$



Siliconized surface: $\theta > 90^\circ$

ORIENTATION OF THE SILICONE MOLECULE ON THE GLASS SURFACE

Siliconization is achieved using an aqueous emulsion of a Polydimethylsiloxanic oil (PDMS), applied inside the vials, conforming to all Pharmacopoeias. The silicone film is fixed and cross-linked to the glass surface inside the annealing Lehr using a heat application process.



Polymer family of siloxanes.
The component is the main constituent
of silicone oil and silicone rubber.
Molecule is described in the Pharma-
copeias monograph.



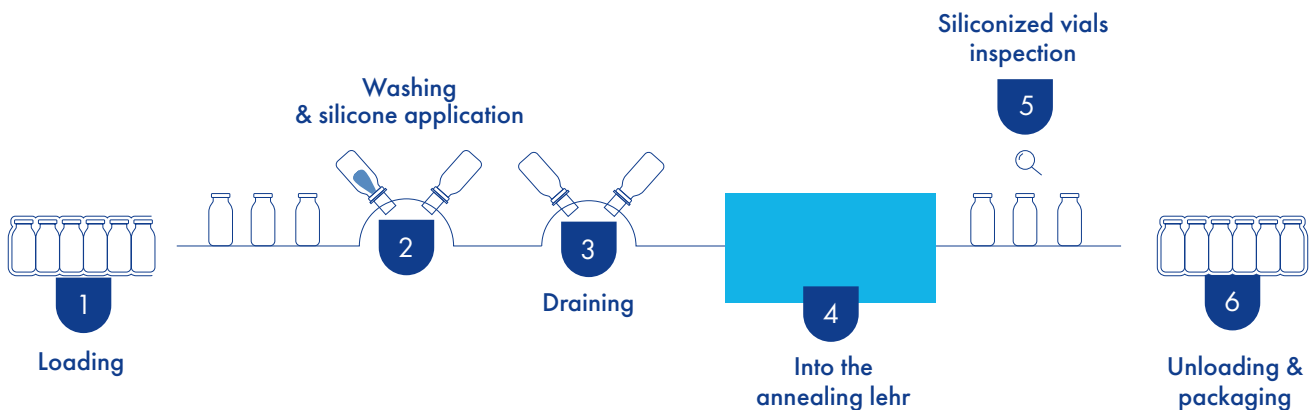


DELIVERING EXCELLENCE

SGD Pharma is a global producer of molded and tubular glass for pharmaceutical primary packaging. Building on over a century of expertise, we provide exceptional quality packaging solutions dedicated to parenteral, oral, and nasal products for every therapeutic application. Our worldwide clients are supported by more than 90 agents and distributors and benefit from ongoing innovation at our five best-in-class ISO 15378 certified, GMP compliant manufacturing plants, giving truly global supply chain infrastructure.



SILICONIZATION PROCESS



1. The vials are delivered in shrink-wrapped packs, they are checked and opened before the vials are loaded onto the siliconization line in a clean room
2. The vials are washed with de-ionized water and the silicone solution is injected inside the vials
3. Excess silicone is removed
4. The silicone film is fixed onto the glass using a heat application process in the annealing lehr
5. Final quality inspection of siliconized vials
6. Packing in clean room and palletisation



Watch the video

Siliconization is carried out in a class 100,000 (ISO 8) cleanroom, with the same quality control standards used during vial production. The expertise and capability of the Verreries de la Somme facility allows us to successfully meet the needs of the most demanding applications.

SGD Pharma deploys state-of-the-art analysis, control and inspection to ensure optimal and consistent product quality.

Process described in FDA Drug Master File DMF12558c.



QUALITY CONTROL

Meticulous quality control of siliconized bottles is carried out during production by systematic manual sampling.

Tests are performed on the siliconized bottles with a synthetic solution, by evaluating how the solution retracts from the glass wall.

To maintain the quality of the coating, siliconized vials should be stored in dry conditions at a moderate temperature.

The silicone coating's resistance will also depend on the chemical structure of the pharmaceutical products.



GLOBAL FOOTPRINT

USE THE KNOWLEDGE AND STRENGTH OF OUR WORLDWIDE NETWORK OF 90 PARTNERS AND DISTRIBUTORS TO YOUR ADVANTAGE.



-  Headquarters
-  Sales office
-  Plant
-  Sorting facility





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